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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,526	06/01/2001	Peter M. Bonutti	BON-1360-7	3309

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EXAMINER	
DAVIS, DANIEL J	
ART UNIT	**PAPER NUMBER**
3731	16

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/872,526	Applicant(s) BONUTTI, PETER	
	Examiner D. Jacob Davis	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *45-56* is/are allowed.

6)☒ Claim(s) *36-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *14,15* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36, 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,804,089 to Bridgman. Robertson discloses on page 444, paragraph 4, that fetal tissue may be used as an "effective therapy" for "severe chronic diseases." He further states, "inserting fetal cells in the affected part of the brain will produce the missing neurotransmitters in quantities sufficient to alleviate symptoms and prevent further deterioration." Furthermore, on page 446, paragraph 1, he states, "The one and a half million abortions performed annually in the United States appear adequate to supply fetal tissue for research and therapy for the foreseeable future." From these statements we learn that A) fetal tissue is implanted in a patient to "alleviate symptoms and prevent further deterioration of some diseases," and B) that the fetal tissue comes from aborted fetuses. What is claimed but not disclosed by Robertson is how the fetus is extracted from a "donor." Although it is not stated in the

claims or the specification whether the donor is the fetus or the mother, the donor is considered the carrier or the mother.

Bridgman teaches a tool (Figs. 1-2) used for performing an abortion under the influence of suction (Abstract). Since the procedure is an abortion, inherently it is performed percutaneously. Col. 2, lines 18-24 disclose that irrigation may occur either "constantly or intermittently." Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Robinson in order to abort the fetus. The fetal tissue inherently is broken into portions during extraction.

Claim 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,804,089 to Bridgman, and in further view of U.S. Patent No. 5,190,541 to Abele et al. Bridgman is silent regarding the fact that irrigation and suction may alternate. Nevertheless, Abele teaches a surgical device that uses irrigation and suction, wherein the suction and irrigation alternate. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to alternate the suction and irrigation (through the same passageway) so that fewer instruments are required to pass through a surgical site.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson

in view of U.S. Patent No. 3,804,089 to Bridgman, and in further view of U.S. Patent No.. Bridgman is silent regarding the fact that irrigation and suction may occur simultaneously. Nevertheless, Wuchinich teaches a surgical device wherein the irrigation and suction occur simultaneously. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the suction and irrigation simultaneous to complete the procedure more quickly.

Claims 36, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,670,732 to Robinson. Robertson meets the limitations of the claims as described but fails to disclose a method of removing the fetus. Nevertheless, Robinson discloses a method of removing the fetus, wherein the tissue is sucked while rotating and reciprocating motion are used to cut the tissue (Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Robinson in order to abort the fetus.

Claims 36 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,939,835 to Bridgman. Robertson meets the limitations of the claims as described but fails to disclose a method of removing the fetus. Nevertheless, Bridgman teaches a method of aspirating and removing an

aborted fetus, including the passage (the collection bottle) having a filter 14 (col. 4 lines 65—col. 5 line 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove the tissue as taught by Bridgman in order to abort the fetus.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Washington University Law Quarterly, "Fetal tissue Transplants," by John A. Robertson in view of U.S. Patent No. 3,939,835 to Bridgman, and in further view of U.S. Patent No. 4,883,666 to Sabel et al. The Robertson/Bridgman method fails to disclose centrifuging the fetal tissue. Nevertheless, Sabel teaches that the "implantation of developing nerve tissue obtained from rat fetus and implanted into brain-damaged host animals reduces behavioral deficiencies due to the lesions." Although rat fetal tissue was mentioned as the tissue source, in col. 2, lines 5-6, Sabel implies that human tissue could be used but would not be due to ethical concerns. Moreover, Robertson teaches that human fetal tissue may be used. In any event, centrifuging must have occurred in order to isolate nerve tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to centrifuge the fetal tissue in order to isolate the nerve tissue.

Allowable Subject Matter

Claims 45-56 are allowed. The prior art fails to disclose or suggest all of the limitations of claim 45 including using any of the tissue material additives. The prior art fails to disclose or suggest all of the limitations of claim 49 including the use of a biodegradable material.

Response to Arguments

Applicant's arguments filed July 2, 2003, with respect to the rejections under 35 U.S.C. 112 and 103 have been fully considered and are persuasive, and the rejections are withdrawn.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
September 23, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700